IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Robert James TRIBE et al.	)
Serial No:	09/920,728	)
Filed:	August 3, 2001	)
For:	SYRINGE PUMPS	) Appeal No.

APPELLANT'S BRIEF ON EX PARTE APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a brief for appealing the final rejecting of pending claims 1, 4, 5 and 7-10 relating to the above-identified application.

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REAL PARTY IN INTEREST

The real party in interest for this appeal is Smiths Group plc, the successor to Smiths Industries plc to whom the inventors had assigned this invention.

RELATED APPEALS AND INTERFERENCES

As far as is known, there are no appeals or interferences that would directly affect or be directly affected by or have a bearing on the Board's decision on the pending appeal.

STATUS OF CLAIMS

Claims 1-10 were presented for prosecution with the filing of the instant application on August 3, 2001. In response to an Office Action dated October 7, 2002, an Amendment dated January 7, 2003 cancelled claims 2, 3 and 6, and amended claims 1, 4, 5, 9 and 10. An Amendment dated June 9, 2003 in response to an Office Action dated March 26, 2003 further amended claims 1 and 7. In response to an Office Action dated August 11, 2003, a response filed on October 24, 2003 did not amend any of the claims. An Office Action dated December 23, 2003 finally rejected all of the pending claims.

The claims at issue in this case and herein on appeal accordingly are claims 1, 4, 5 and 7-10, as reproduced in Appendix A.

STATUS OF AMENDMENTS

There was no Amendment filed subsequent to the final rejection Office Action dated December 23, 2003.

SUMMARY OF THE INVENTION

The instant invention, as set forth in claim 1, relates to a syringe pump that is used to supply medication to a patient. The syringe pump is adapted to receive a syringe (3) having a plunger (35) that is movable along a barrel (30). The pump includes a drive mechanism (7) that moves the plunger along the barrel, and an occlusion detector that includes a force sensor (2) that is responsive to occlusion to

the flow of medication from the syringe, so that when an occlusion is detected, the pump operates to reverse the movement of the plunger sufficiently until the force detected by the force sensor falls by a predetermined amount. [page 4, lines 4-17][1]

Additional variants of the instant invention are set forth in independent claims 5 and 7. Claim 5 in particular recites a syringe pump that includes a drive mechanism having a motor (9), a lead screw (8) driven by the motor and a plunger retainer (10) that is movable along the lead screw so as to move the plunger along a barrel, and a force sensor (20) mounted with the plunger retainer to detect excess force on the plunger. For the claim 5 variant, when the force sensor detects an excessive force, the motor is reversed until the output of the force sensor indicates an absence of an excessive force. [page 4, lines 4-17]

Claim 7 defines a method of controlling a syringe pump that includes the steps of: applying a force to drive a plunger (35) along a barrel (30) of a syringe (3) to dispense medication; detecting the force on the plunger; and responding to a force on the plunger above a predetermined value by changing the direction of force applied to drive the plunger to reduce the detected force below a predetermined value. [page 4, lines 4-17]

The claimed syringe pump, and method therefor, thus requires a force sensor that is responsive to occlusion. When an excess force indicative of occlusion is detected, the drive the syringe pump is reversed until the force detected by the force sensor falls by a predetermine amount. The instant inventive syringe pump therefore prevents an excessive fluid pressure being built up within the tubing after an occlusion is cleared so as to ensure that the fluid pressure is relieved to a safe level without any risk of a negative pressure being created that might lead to an excessively large bolus of medication being administered.

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[1] The designations of the different elements recited in the claims are in parentheticals while the pages of the disclosure that provide support for the claims are bracketed.

ISSUES

The sole issue being presented herein on appeal is whether the rejection of claims 1, 4, 5 and 7-10 under 35 U.S.C. 102(e) as being anticipated by Moberg et al. U.S. patent 6,362,951, is sustainable.

GROUPING OF CLAIMS

The being appealed claims, as discussed above in the Summary of Invention section, include independent claims 1, 5 and 7. Insofar as the independent claims present different scopes of coverage of the instant invention, appellants respectfully request that each of the independent claims be considered separately as each is separately patentable over the prior art, as will be discussed hereinbelow.

ARGUMENT

Appellants respectfully submit that each of claims 1, 4, 5 and 7-10 is not anticipated by Moberg '951.

"Anticipation under 35 U.S.C. 102(e) requires that 'each and every element set forth in the claim is found either expressly or inherently described in a single prior art reference'." In re Robertson, 169 F.3d 743, 746 (Fed. Cir. 1999).

Claim 1 recites a syringe pump that comprises an occlusion detector that includes a force sensor (20), and the drive applied to move the plunger along the barrel is reversed sufficiently until the force detected by the force sensor falls by a predetermined amount. Claim 5 recites the force sensor being mounted with the plunger retainer to detect excess force on the plunger so that when the force sensor detects an excess force, the motor is reversed until the output from the force sensor indicates an absence of an excessive force.

For the method of claim 7, a force is detected on the plunger, and if the detected force is above a predetermined value, the direction of force applied to drive the plunger is changed such that the detected force is reduced below the predetermined value.

For each of independent apparatus claims 1 and 5, there is therefore recited in particular a force sensor that detects either an occlusion (claim 1) or an excess force (claim 5); and in response to the detected occlusion/force, the drive for the syringe pump is reversed so that the force that is detected by the force sensor would either fall by a predetermined amount (claim 1) or when an excessive force is no longer detected (claim 5). The method of claim 7 requires the detection of a force on the plunger, and the responding to the detected force on the plunger above a predetermined value.

Moberg '591, on the other hand, does not disclose any force sensor that is to be used with a syringe pump. Indeed, the system disclosed in Moberg '591 aims to eliminate the use of such force sensors. This is apparent starting with the disclosure in the Background of the Invention section where Moberg discloses that prior infusion pumps such as those disclosed in U.S. patents 4,562,751 and 4,678,408, which do include "a high pressure limit switch", tend to have several disadvantages. See column 2, lines 5-23. Thus, seeking to avoid the use of force sensors because of the perceived problems as noted in the Background of the Invention section, Moberg went on to disclose three embodiments for detecting occlusions or pump failures without the use of a force sensor.

The first embodiment indirectly measures the pump motor current value. This embodiment is summarized in column 2, lines 35-44 and disclosed in detail from column 3, line 32 to column 9, line 18. The flow chart in which the current of the motor is measured to indicate indirectly an occlusion is given in Fig. 5. In particular, in block 507, the motor current is measured. And if there is an occlusion in the system, the pressure of the fluid in the reservoir is increased. That in turn causes greater motor torque and current as the motor attempts to advance the reservoir plunger against this fluid pressure. This measured current is then compared with an established base line to determine if there is any occlusion (Column 7, lines 2-13). Thus, for the first syringe pump embodiment disclosed by Moberg, there is no force sensor disclosed, as the motor current, or some other parameters relating to the

motor (column 8, lines 30-35) are measured indirectly to determine whether there is an occlusion.

The second embodiment disclosed by Moberg likewise does not disclose any physical force sensor. For the second embodiment, Moberg discloses the use of a motor position encoder that measures the rotational count of the motor. The operation of this second embodiment is given in detail from column 8, line 36 to column 10, line 21; and its operation is specifically shown in the flow chart of Fig. 6 where blocks 606, 607 and 609 particularly illustrate the measuring of the encoder count, the reading of the encoder alarm limit, and the comparison of the count with an alarm limit, respectively. Again, for the second syringe pump embodiment of Moberg, there is no disclosure of any physical force sensor.

Moberg extends his indirected measurement technique in a third embodiment which summary is provided in column 2, line 66 to column 3, line 10 and the detailed disclosure given in column 10, line 22 to column 11, line 27. For this embodiment, by using the encoder count, the torque of a motor is measured. The flow diagram illustrating the third embodiment is given in Fig. 7. The use of the encoder count for determining the torque from a look up table and the comparison of the torque with the allowable limit are steps that are provided in blocks 706, 707 and 708, respectively, of the Fig. 7 flow chart. Like the earlier two embodiments, the third embodiment of Moberg does not utilize any physical force sensors. Again, it is based on the indirect measurement of a given parameter of a motor for determining whether there is an occlusion in the system.

A succinct summary of the indirect detection of an occlusion in the drive system of the various Moberg embodiments is given in column 11, lines 28-42.

The examiner had argued that since Moberg had incorporated by reference the disclosure of Nason U.S. patent 4,678,408 and since the '408 patent does show a high pressure limit switch, then the disclosure of Moberg would anticipate the at issue claims.

The mechanical construction of the Moberg device is given in Figs. 1-4. Note in particular Fig. 4 which shows the motor 404 having connected to its one end an encoder wheel 412 and an encoder sensor 406, with an output to an encoder logic 407. It is unfortunate that Moberg refers to the set up shown in Fig. 4 as an "improved occlusion detector" which may be applied to the pump drive designs of Figs. 1-3 (column 5, lines 33-34). Yet Moberg went on to clarify that an improved occlusion detector is one that "measures increased reservoir pressure indirectly by monitoring one or more motor parameters such as voltage, current, running time, or rotational or linear displacement." (column 5, lines 38-42). To explain the rationale behind the use of such "indirect" measuring method for determining occlusion, Moberg went on to state: "It is known in the art that torque developed by a brushed DC motor is directly proportional to the current supplied to it at steady state. Therefore, in a screw type drive system, as the axial load increases due to increased fluid pressure within the reservoir, more motor torque is required to drive the system. Should there be an occlusion, the pressure inside the reservoir will exceed a predetermined threshold. Thus, the current necessary to drive that load will exceed a predetermined current threshold and the electronics will be flagged to cease further delivering. In addition, an audible, tactile and/or display alarm typically is triggered." (Column 5, lines 43-55).

It is thus clear that there is no actual physical force sensor in the Moberg device, as Moberg defines his "improved occlusion detector" as a system that indirectly measures an occlusion in the syringe pump, in accordance to his aim of steering clear of prior art pumps that do use high pressure limit switch. According to Moberg, such high pressure limit switch pumps are exemplified by U.S. patent 4,562,751. (Column 1, line 58 to column 2, line 4 and again in column 4, line 29).

U.S. patent 4,678,408 is a continuation of U.S. patent 4,562,751,[2] which is described by Moberg as a prior art medication infusion pump that has disadvantages

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[2] Per Appendix B, note that Nason et al. U.S. Patent 4,678,408 matured from application No. 779,733, which in turn was a continuation of application No. 568,615. Per Appendix C, note that Nason et al. U.S. patent 4,562,752 matured from application No. 568,615.

which the Moberg invention aims to overcome (column 1, line 58 to column 2, line 4). A careful reading of the paragraph in column 4, lines 14-30, which is relied upon by the examiner, shows that U.S. patent 4,678,408 (and also U.S. patent 4,562,571 which should be 4,562,751) were disclosed by Moberg to provide general details regarding the construction and operation of a medication infusion pump. There is no disclosure or suggestion by Moberg that the high pressure limit switch disclosed in either the '408 or '751 patent is to be any part of the Moberg system. Quite the contrary, as supported by the disclosure in the Background of the Invention section, Moberg clearly teaches his invention away from the prior art medication infusion pumps that use a high pressure limit switch, as disclosed by U.S. patent 4,678,408 and 4,562,751. Accordingly, as Moberg specifically teaches away from the use of a direct force sensor to measure increased reservoir pressure and indeed contrast his invention from such direct force sensor pumps, there clearly is no teaching in Moberg of, or motivation for, using a force sensor to trigger a pump to reverse its drive in response to an excess pressure.

In view of the foregoing, appellants respectfully submit that the being appealed claims are not anticipated by Moberg '951. Accordingly, the rejection of the being appealed claims is respectfully requested to be reversed.

Respectfully submitted,

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Date: April 27, 2004

APPENDIX A

1. A syringe pump adapted to receive a syringe having a plunger movable along a barrel, the pump comprising: a drive mechanism for moving said plunger along said barrel; and an occlusion detector responsive to occlusion to flow of medication from said syringe, said occlusion detector including a force sensor, wherein the pump is operable in response to a detected occlusion to reverse the drive applied to move said plunger along said barrel sufficiently until the force detected by said force sensor falls by a predetermined amount.

4. A pump according to Claim 1, wherein the pump is arranged to reverse the drive until force detected by said force sensor is substantially 10% of the force at which an occlusion is detected.

5. A syringe pump adapted to receive a syringe having a plunger movable along a barrel, the pump comprising: a drive mechanism, said drive mechanism including a motor, a leadscrew driven by said motor and a plunger retainer movable along the leadscrew such as to move said plunger along said barrel; and a force sensor mounted with said plunger retainer to detect excess force on said plunger, wherein the pump is operable in response to an output from said force sensor indicative of an excess force to reverse said motor until the output of said force sensor indicates an absence of an excessive force.

7. A method of controlling a syringe pump comprising the steps of: applying a force to drive a plunger along a barrel of a syringe to dispense medication; detecting force on said plunger; responding to a force on said plunger above a predetermined value by changing the direction of force applied to drive said plunger such that said detected force reduces below said predetermined value.

8. A method according to Claim 7, wherein force applied to drive said plunger is changed to reduce said detected force to substantially 10% of said predetermined value.

9. A method according to Claim 7, wherein the pump generates an alarm when force on said plunger exceeds a predetermined value.

10. A method according to Claim 7, wherein the pump only reapplies force to dispense medication when the pump is manually restarted after detection of an occlusion

United States Patent [19]

Nason et al.

[11] **Patent Number: 4,678,408**

[45] **Date of Patent: Jul. 7, 1987**

[54] **SOLENOID DRIVE APPARATUS FOR AN EXTERNAL INFUSION PUMP**

[75] Inventors: **Clyde K. Nason, Valencia; Gordon W. Culp, Van Nuys, both of Calif.**

[73] Assignee: **Pacesetter Infusion, Ltd., Sylmar, Calif.**

[21] Appl. No.: **779,733**

[22] Filed: **Sep. 24, 1985**

Related U.S. Application Data

[63] Continuation of Ser. No. 568,615, Jan. 6, 1984.

[51] **Int. Cl.**[4] **F04B 9/06; F04B 13/00**

[52] **U.S. Cl.** **417/410; 74/128; 74/142**

[58] **Field of Search** 417/22, 410; 74/126, 74/128, 142

[56] **References Cited**

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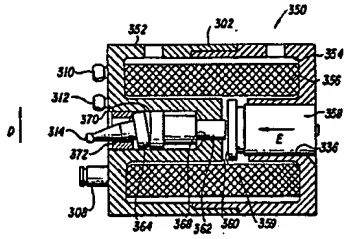
4,562,751	1/1986	Nason et al.	74/111

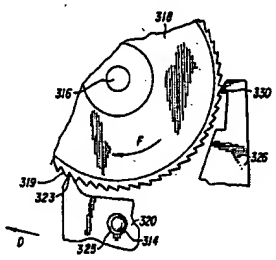
Primary Examiner—Carlton R. Croyle
Assistant Examiner—Ted Olds
Attorney, Agent, or Firm—Leslie S. Miller; Bryant R. Gold

[57] **ABSTRACT**

A solenoid drive apparatus for driving a lead screw of an External Infusion Pump (1) having a housing (302), solenoid winding (356) within the housing (302), a solenoid armature (358) which is driven by the field of the solenoid winding (356), push rod (362) which is driven by the armature (358), pawn (314) which is driven by push rod (362), a first pawl (320) which is driven by pawn (314) and a second pawl (326) which is an anti-backlash device, a ratchet wheel (318) having teeth (319) around its periphery and engaged by the first pawl (320) and the second pawl (326) and the drive shaft (316) which is drawn by the ratchet of the ratchet wheel (318).

11 Claims, 14 Drawing Figures





United States Patent [19]

Nason et al.

[11] **Patent Number: 4,562,751**

[45] **Date of Patent: Jan. 7, 1986**

[54] **SOLENOID DRIVE APPARATUS FOR AN EXTERNAL INFUSION PUMP**

[76] Inventors: Clyde K. Nason, 25745 N. Player Dr., Valencia, Calif. 91355; Gordon W. Culp, 13832 Haynes St., Van Nuys, Calif. 91401

[21] Appl. No.: **568,615**

[22] Filed: **Jan. 6, 1984**

[51] **Int. Cl.**[4] **F16H 27/02**

[52] **U.S. Cl.** **74/111; 74/128**

[58] **Field of Search** 74/111, 128

[56] **References Cited**

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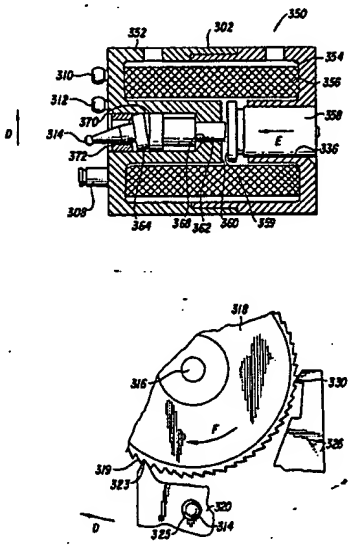
Primary Examiner—Henry C. Yuen

Attorney, Agent, or Firm—Robert R. Meads; Bryant R. Gold

[57] **ABSTRACT**

A solenoid drive apparatus for driving a lead screw of an External Infusion Pump (1) having a housing (302), solenoid winding (356) within the housing (302), a solenoid armature (358) which is driven by the field of the solenoid winding (356), push rod (362) which is driven by the armature (358), pawn (314) which is driven by push rod (362), a first pawl (320) which is driven by pawn (314) and a second pawl (326) which is an anti-backlash device, a ratchet wheel (318) having teeth (319) around its periphery and engaged by the first pawl (320) and the second pawl (326) and the drive shaft (316) which is drawn by the ratchet of the ratchet wheel (318).

8 Claims, 14 Drawing Figures



CITATIONS

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IWF AF 3763

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For:	SYRINGE PUMPS	)	Attorney Docket: 0100/0131

FEE AUTHORIZATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Commissioner is hereby authorized to debit the amount of $330.00 from Deposit Account No. 50-0501 for the filing of the accompanying Appeal Brief for the above-identified Application.

The Commissioner is further hereby authorized to debit funds from Deposit Account No. 50-0501 if the amount noted above is insufficient. A duplicate copy of this letter is attached.

Respectfully submitted,

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Date: April 27 2004